

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT EXAMINING OPERATION

Applicants: Nitin Sopanrao PATIL et al.

Serial No: 10/596,227

Group Art Unit:

Filed: June 5, 2006

Examiner:

Att. Docket No.: A1181/20002

Confirmation No.: 3774

For: PROCESS FOR THE PURIFICATION OF MACROLIDES

IDS CERTIFICATION STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO/SB/08a. Unless otherwise indicated herein, one copy of each reference is attached. No copies of U.S. patents or U.S. patent application publications are attached. 37 CFR § 1.98(a)(2)(ii). It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. No representation is made that the references are prior art with respect to this application.

This Information Disclosure Statement is being filed within three months of the filing date of a national application other than a CPA under 37 CFR § 1.53(d), within three months of the date of entry of the national stage as set forth in 37 CFR § 1.491 in an international application, before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of an RCE under 37 CFR § 1.114. No certification or fee is required. 37 CFR § 1.97(b).

The references were cited in a counterpart foreign application. An English language version of the foreign search report is attached for the Examiner's information.

Application No. 10/596,227  
IDS Certification Statement dated July 28, 2006

The references were cited in the International Search Report of the counterpart international application of this national stage application. As noted on the Notice of Acceptance, the PTO received from the international office copies of the International Search Report and the references cited therein. Thus, copies of the Report and the references cited therein are not attached. See MPEP 1893.03(g)

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

July 28, 2006

Please charge or credit our Account  
No. 03-0075 as necessary to effect  
entry and/or ensure consideration of  
this submission.

By Marina E. Volin  
Marina E. Volin  
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Customer No. 03000  
(215) 567-2010  
Attorneys for Applicants

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10596227
Filing Date		2006-06-05
First Named Inventor	Nilin Sopanrao PATIL et al.	
Art Unit		
Examiner Name		
Attorney Docket Number	A1181/20002	

**U.S.PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4734492		1988-03-29	TANBA et al.	
	2	5508398		1996-04-16	GLETSOS	
	3	5616595		1997-04-01	CHU et al.	
	4	6492513	B1	2002-12-10	NISHIHARA et al.	
	5	6576135	B1	2003-06-10	HIGAKI et al.	
	6	4894366		1990-01-16	OKUHARA et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

**U.S.PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	0 184 162	EP	B1	1994-04-27	Fujisawa Pharmaceutical Co., Ltd.		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	Sangler JJ et al, "Sanglifehrins A, B, C and D, novel cyclophilin-binding compounds isolated from streptomyces sp. A82-308110. I. Taxonomy, fermentation, isolation and biological activity" J Antibiot (Tokyo). 1999 May;52(5):466-73	<input type="checkbox"/>
	2	Weizhong Wang-Fan et al, "Application of centrifugal counter-current chromatography to the separation of macrolide antibiotic analogues I. Selection of solvent systems based on solubility and partition coefficient investigations" Journal of Chromatography A, 864 (1999) 69-76	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached

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Examiner Name	
Attorney Docket Number	A1181/20002

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

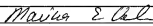
OR

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☒ See attached certification statement.
- ☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2006-07-28
Name/Print	Marina E. Volin	Registration Number	52,328

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**